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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/688,017	10/13/2000	Peter S. Lu	20054-001110US	7473

20350 7590 07/28/2003

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EXAMINER

BELYAVSKYI, MICHAEL A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 07/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/688,017

Applicant(s)

LU ET AL.

Examiner

Michail A Belyavskyi

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1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 23-50 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 27-37 and 43-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-26 and 38-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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RESPONSE TO APPLICANT'S AMENDMENT

The **examiner** of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Michail Belyavskiy, Group Art Unit 1644, Technology Center 1600

1. Applicant's amendment, filed 5/19/03 (Paper No. 13), is acknowledged.

Claims 1-7 and 23-50 are pending.

2. The amended claims 31 –34 and newly submitted claims 43-50 directed to an inventions that are independent or distinct from the invention originally claimed for the following reasons: The elected claims 23-26 are drawn to a method for identifying an interaction between a PDZ domain and PDZ ligand protein, comprising contacting at least one PL protein to an array of at least 5 PDZ-containing polypeptides of different amino acid sequence. The amended claims 31-34 are drawn to a method for determining binding affinity between a PDZ domain and PDZ ligand protein and newly submitted claims 43-50 drawn to a to a method for identifying an interaction between a PDZ domain and PDZ ligand protein, comprising contacting a PL fusion protein to an immobilized PDZ fusion protein. These inventions are differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct. A different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 1-7, 27-37 , 31-34 and 43-50 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 23-26 and 38-42 read on a method for identifying an interaction between a PDZ domain and PDZ ligand protein, comprising contacting at least one PL protein to an array of at least 5 PDZ-containing polypeptides of different amino acid sequence and under consideration in the instant application.

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The following new ground of rejections are necessitated by the amendment filed 5/19/03 (Paper No. 13).

3. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 23-26 and 38-42 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 is indefinite and ambiguous in the recitation “a method for identifying an interaction between a PDZ domain and a PDZ ligand protein...” It is not clear if Applicants intended to identify an interaction between “PDZ domain” or “a PDZ domain containing polypeptides” ? It is suggested that said phrase be change to “ a PDZ domain containing polypeptides” for clarity and consistence with the disclose of the specification.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 23-26 and 38-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gee et al (J. neuroscience, 1988, 18(1):128-137) in view of the known fact disclosed in the Specification on page 53, lines 25-33 and further in view of the Coligam et al. (Current Protocols in Immunology, 1991, pages 2.03-2.1.9).

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Gee et al. teach a method for identifying an interaction between a PDZ domain containing polypeptides (such as a PDZ domain from SKM1 or from SKM2 and a PL protein (a PDZ ligand protein) comprising contacting the PL protein (i.e. either SKM1 or SKM2) to a plurality of PDZ containing polypeptides (such as contained in detergent solubilized heat membranes) and detecting at least one PL protein (i.e. syntrophin), (see entire article, including Fig.4). Gee et al. teach that there is an interaction between a protein PL (i.e. syntrophin) and more than one PDZ (i.e. SKM1 and SKM2).

Gee et al. also teach a method for identifying an interaction between a PDZ domain containing polypeptides (such as a PDZ domain from SKM1 or from SKM2 and a PL protein (a PDZ ligand protein) comprising contacting the PL protein (i.e. either SKM1 or SKM2) to a plurality of PDZ containing polypeptides (such as alpha -1 syntrophin, beta-1 syntrophin, or beta-2 syntrophin) organized in an array such as in different lanes of a blot, (see entire document, Fig.5B in particular).

Gee et al. does not teach: a) an array of at least 5, or at least 25, or at least 40 PDZ containing polypeptides; b) binding between at least one PL protein to one or more of the PDZ-containing polypeptides is detected by ELISA ; c) PDZ -containing polypeptides are immobilized in a well of a microtiter plate.

The known fact disclosed in the Specification on page 53, lines 25-33 that a variety of reliable and rapid assay formats are known in the art for characterization of the specific PDZ-PL interaction, including solid-phase ELISA, immunoassays and immunoprecipitation.

Coligam et al. teach that solid-phase ELISA method of detecting interaction between proteins comprises immobilizing one of the binding proteins to the well of a microtiter plate (see entire document pages 2.03-2.1.9 in particular). Coligam et al. also teach that in order to determine an interaction between proteins a statistical difference between a signal representative of a complex and a signal for a control are performed (see entire document, pages 2.03-2.1.9 in particular).

A method for identifying an interaction between a PDZ domain containing polypeptides and a PL protein taught by Gee et al., differ from a claimed methods only by recitation of an array of at least 5, or at least 25, or at least 40 PDZ containing polypeptides. It is clear that both the prior art and applicant administer the same method to achieve the same results. Therefore, it would be obvious and conventional and within the skill of the art to identify and determine the optimum number of different PDZ-containing polypeptides in an array. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP § 2144.05 part II A.

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In addition, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to apply the teaching of the known fact disclosed in the Specification on page 53, lines 25-33 and of the Coligam et al. to those of Gee et al., to obtain a claimed method for identifying an interaction between a PDZ domain containing protein and PL protein, wherein binding between the at least one PL protein to one or more of the PDZ-containing polypeptides is detected by ELISA, wherein each of the PDZ-containing polypeptides are immobilized in a well of a microtiter plate.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so, because ELISA is a well known, reliable and rapid assay formats for characterization of the specific PDZ-PL interactions, comprising immobilizing one of the binding proteins (i.e. PDZ-containing polypeptide to the well of a microtiter plate), comprising determining a statistical difference between a signal representative of a complex and a signal for a control as taught by the known fact disclosed in the Specification on page 53, lines 25-33 and of the Coligam et al., that can be used in a method for identifying an interaction between a PDZ domain and a PL protein taught by Gee et al..

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

7. No claim allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

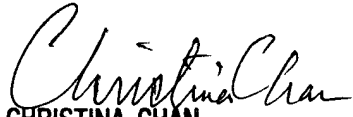
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is (703) 308-4232. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Michail Belyavskiy, Ph.D.
Patent Examiner
Technology Center 1600
July 28, 2003


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